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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/608,094	Applicant(s) SARAF, RAVI F.	
	Examiner Teresa E. Strzelecka	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 160-163 and 165-200 is/are pending in the application.
- 4a) Of the above claim(s) 167-200 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 160-163, 165 and 166 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This case was transferred to examiner Teresa Strzelecka because examiner Jeffrey Fredman left the art unit.
2. This office action is in response to an amendment filed October 15, 2007. Claims 160-163 and 165-200 were previously pending, with claims 167-200 withdrawn from consideration. Applicant amended claim 160. Claims 160-163, 165 and 166 will be examined.
3. Applicant's amendment overcame the previously presented rejections. Consequently, Applicant's arguments are moot in view of the new grounds for rejection presented in the office action below.

Claim Interpretation

4. Applicant did not define the term "insertion compound", therefore it is interpreted as any compound.
5. Applicant did not define the term "attaching", as in "attaching an insertion compound", therefore any form of interaction between a nucleotide and the insertion compound, whether covalent or not, is considered as "attachment".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 160-163 and 165 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller (U.S. Patent No. 6,017,696; cited in a previous office action).

Heller teaches a method comprising:

a) *Providing a substrate having defined therein an array of periodically spaced regions capable of defining a writable segment in a nucleic acid molecule at one or more locations where said periodically spaced regions contact said nucleic acid molecule* (see figures 8 and 9, column 7, lines 5-31, where thousands of sites are taught and column 46, example 12, where Heller teaches the APEX chips which have nucleic acids located in multiple different micro locations),

b) *Providing at least one double stranded nucleic acid molecule on said substrate thereby defining a plurality of said writable segments in said nucleic acid molecule at one or more locations where said periodically spaced regions are in contact with said nucleic acid molecule* (see column 46, example 12, where double stranded DNA is formed on the array in each microlocation as shown in lines 25-45),

c) *denaturing at least one of said writable segments by heating at least one of said writable segments by passing electrical current through a metal element arranged in or on the substrate* (see column 46, lines 63-67 to column 47, lines 1-3, where Heller teaches denaturation of the segments placed on electrodes which are metal elements, as Heller notes at column 32, example 5, where aluminum and gold are used. Further, when Heller teaches passing voltage through the element, this also means current is passing through the element as per $V=IR$),

d) *attaching at least one insertion compound to at least one nucleotide in said at least one writable segment, wherein the insertion compound reacts with an amine group and prohibits renaturing said denatured segment* (Heller teaches amplification of target DNA using capture probes attached to electrodes (Fig. 17; col. 46, lines 25-67; col. 47, lines 1-35), therefore, as can be seen in Fig. 17, the step of binding (=attaching) a reverse primer (=insertion compound) prevents renaturing of the target to the ML-1 capture probe. Since the bases of nucleic acids have amino groups, the primer interacts with the amino groups by hydrogen bonding. Further, Heller teaches electronic in situ hybridization (col. 23, lines 48-64), where the DNA inside cells is hybridized with the reporter probe, therefore, Heller inherently teaches denaturing double-stranded DNA within cells and binding (=attaching) a probe, which interacts with the target amino groups via hydrogen bonding and prevents renaturing of the double stranded DNA within cells).),

wherein said information is defined by the presence or absence of said insertion compound (see column 47, lines 20-35, and col. 23, lines 48-64, where the information in the sequences is defined by whether amplification occurs or not or whether the probe binds or not).

With regard to claim 161, Heller teaches incorporation of a primer or a probe (see column 47, lines 4-11, or col. 23, lines 48-64), therefore they inherently teach the insertion compound attached to at least one nucleotide.

With regard to claims 162-163, Heller teaches the use of fluorescent labels to label the DNA probes or target DNAs (see column 26, lines 5-11, for example).

With regard to claim 165, Heller teaches heating using electrical current through a metal element arranged in the substrate (see column 46, lines 65-67 and column 47, lines 1-3, where voltage is applied through the electrode on the chip to denature the sample which will heat the sample).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 166 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (U.S. Patent 6,017,696).

A) Heller teaches a method comprising:

a) *Providing a substrate having defined therein an array of periodically spaced regions capable of defining a writable segment in a nucleic acid molecule at one or more locations where said periodically spaced regions contact said nucleic acid molecule* (see figures 8 and 9, column 7, lines 5-31, where thousands of sites are taught and column 46, example 12, where Heller teaches the APEX chips which have nucleic acids located in multiple different micro locations),

b) *Providing at least one double stranded nucleic acid molecule on said substrate thereby defining a plurality of said writable segments in said nucleic acid molecule at one or more locations where said periodically spaced regions are in contact with said*

nucleic acid molecule (see column 46, example 12, where double stranded DNA is formed on the array in each microlocation as shown in lines 25-45),

c) *denaturing at least one of said writable segments by heating at least one of said writable segments by passing electrical current through a metal element arranged in or on the substrate* (see column 46, lines 63-67 to column 47, lines 1-3, where Heller teaches denaturation of the segments placed on electrodes which are metal elements, as Heller notes at column 32, example 5, where aluminum and gold are used. Further, when Heller teaches passing voltage through the element, this also means current is passing through the element as per $V=IR$),

d) *attaching at least one insertion compound to at least one nucleotide in said at least one writable segment* (Heller teaches amplification of target DNA using capture probes attached to electrodes (Fig. 17; col. 46, lines 25-67; col. 47, lines 1-35), therefore, as can be seen in Fig. 17, the step of binding (=attaching) a reverse primer (=insertion compound) prevents renaturing of the target to the ML-1 capture probe. Since the bases of nucleic acids have amino groups, the primer interacts with the amino groups by hydrogen bonding. Further, Heller teaches electronic in situ hybridization (col. 23, lines 48-64), where the DNA inside cells is hybridized with the reporter probe, therefore, Heller inherently teaches denaturing double-stranded DNA within cells and binding (=attaching) a probe, which interacts with the target amino groups via hydrogen bonding and prevents renaturing of the double stranded DNA within cells).),

wherein said information is defined by the presence or absence of said insertion compound (see column 47, lines 20-35, and col. 23, lines 48-64, where the information

in the sequences is defined by whether amplification occurs or not or whether the probe binds or not).

B) Heller teaches oscillating the current (col. 40, lines 29-32), but Heller does not specifically teach the use of 100 nanosecond pulses.

Heller does, however, teach "The amount of voltage and the time period of application will be dependent on the length and base composition of the hybrid DNA complex (see column 46, line 66 to column 47, line 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the routinely optimized time for application of current since Heller teaches "The amount of voltage and the time period of application will be dependent on the length and base composition of the hybrid DNA complex (see column 46, line 66 to column 47, line 1). An ordinary practitioner would have recognized that the optimizable variables of pulse length of the current could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific times for current application was other than routine, that the products resulting from that optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

10. No claims are allowed.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka

4/25/07